IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INTERNATIONAL UNION OF BRICKLAYERS AND ALLIED CRAFT WORKERS LOCAL 1 HEALTH FUND, Plaintiff, v. CELGENE CORPORATION, Defendant.	CIVIL ACTION NO. 2:14-cv-06997 (KSH/CLW) **Return Date: March 2, 2015**

DEFENDANT CELGENE CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

The Complaint by plaintiff International Union Of Bricklayers and Allied Craft Workers Local 1 Health Fund ("IUB") should be dismissed, because it fails to state any cognizable claim under federal or state law.

First, IUB's claims, whether asserted under federal or state law, all suffer from a fundamental, and incurable, defect of causation. This is because each of IUB's claims is premised on an allegation that (i) defendant Celgene Corporation ("Celgene") did something allegedly improper to delay generic drug manufacturers from entering the market with copycat versions of Celgene's brand-name drugs Revlimid® and Thalomid®, and (ii) this allegedly harmed IUB, because IUB paid more to cover the cost of Revlimid and Thalomid prescribed to IUB members than IUB would have paid with generic competition for those drugs.

As IUB's Complaint acknowledges, however, Celgene has an extensive patent portfolio covering Revlimid and Thalomid. Indeed, that portfolio includes more than 40 patents that Celgene has already asserted, and/or can assert in the future, to bar others from selling generic versions of Revlimid and Thalomid. It is these patents, and not anything alleged in the Complaint, that explain the absence of generic competition.

Under the well-established *Noerr-Pennington* doctrine, Celgene ***cannot be held liable*** for asserting its patents to preclude generic competition unless the patents in

that portfolio were either procured by fraud on the U.S. Patent and Trademark Office ("PTO") or asserted without any objective basis (that is, a "sham" assertion).

Yet of the many patents in Celgene's relevant portfolio, the Complaint here alleges that only *six* – the so-called Distribution Method Patents[1] – were purportedly fraudulently procured or sham asserted. The Complaint does not (and could not legitimately) allege that Celgene's nearly three dozen other patents covering Revlimid and Thalomid were the subject of either fraud on the patent office or a sham assertion. These nearly three dozen other patents thus stand as a bar to all of IUB's claims, since Celgene as a matter of law can assert those patents, so long as they have not been declared invalid, to protect Celgene's presumptively valid intellectual property. Under the *Noerr-Pennington* doctrine, IUB's mere allegations here that these patents are invalid (as opposed to fraudulently procured or the subject of sham assertion) are insufficient as a matter of law to undermine Celgene's right to assert, and continue asserting, those patents.

Thus, even if all of IUB's allegations of Celgene's purported improper conduct were true, IUB could never establish that this conduct ***caused*** generic versions of Revlimid and Thalomid not to come to market. No generic manufacturer could have

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[1] In its Complaint, IUB only explicitly labels U.S. Patent Nos. 6,045,501, 6,315,720, 6,651,976, 6,561,977, and 9,755,784 the "Distribution Method Patents." It then apparently includes U.S. Patent No. 8,315,886 in that definition later in its Complaint. To avoid confusion, Celgene will refer to all six of the patents herein as the "Distribution Method Patents." (*See* Compl. ¶ 124.)

brought generic versions of Revlimid and Thalomid to market in any event, for the wholly independent reason that, as a matter of law, Celgene can assert (and has asserted) patents in its portfolio that IUB does not, and could not legitimately, challenge as having been fraudulently procured or sham asserted. The absence of causation precludes all of IUB's claims.

Second, IUB also cannot pursue any damages claims under federal antitrust law, or state antitrust and consumer protection laws, for the independent reason that IUB did not directly purchase Revlimid and Thalomid from Celgene, and both federal antitrust law, and any applicable state laws, bar an ***indirect*** purchaser such as IUB from pursuing damages claims.

Presumably recognizing that *Illinois Brick Company v. Illinois*, 431 U.S. 720 (1977), barred indirect purchaser claims under federal law, IUB purports to pursue damages claims under various state antitrust and consumer protection laws. But fundamental standing principles preclude IUB from pursuing such claims except under the laws of states where IUB itself either resides or allegedly overpaid for the two drugs – here, Connecticut (which the Complaint states is IUB's principal place of business), or Massachusetts and Nebraska (the states where the Complaint alleges IUB overpaid). Under New Jersey's applicable choice of law rules, IUB's state law claims are all governed by Connecticut law, which precludes indirect purchaser damages claims.

The foregoing defects alone are dispositive and require dismissal of IUB's Complaint, and cannot be remedied by amended pleadings. The Complaint here suffers from other deficiencies as well, discussed below. Celgene therefore respectfully submits this that Court should dismiss IUB's Complaint in its entirety, and with prejudice.

STATEMENT OF FACTS

A. Celgene Develops Thalomid and Revlimid and Establishes Breakthrough REMS Programs.

Celgene is a biopharmaceutical company. As a branded manufacturer, Celgene devotes substantial resources to researching and developing new medicines for a variety of diseases and ailments. (*See* Compl. ¶ 22.) Two of Celgene's most well-known products are Thalomid® and Revlimid®, whose generic names are, respectively, thalidomide and lenalidomide. (*See* Compl. ¶¶ 67, 69.)

Thalidomide was originally marketed in the 1950s and 1960s by a company other than Celgene as a sleeping pill for pregnant women, but the drug caused serious birth defects and other side effects. (Compl. ¶ 66.) In light of this, thalidomide was banned for over 30 years until Celgene developed the drug as a treatment for a form of leprosy. (Compl. ¶ 67.) Given thalidomide's substantial risks, the FDA would not permit any company to distribute a thalidomide-based medicine without first developing a safe method of delivering the drug without risk of fetal exposure, now known as a Risk Evaluation and Mitigation Strategy ("REMS"). (*Id.*) Celgene took

on that challenge and obtained FDA approval for Thalomid only once it developed and implemented its innovative System for Thalidomide Education and Prescribing Safety, or "S.T.E.P.S.®" (*Id.*) Among other things, S.T.E.P.S., now known as the Thalomid REMS, required distributors, pharmacists, and recipient patients to enroll in a comprehensive monitoring program. (*Id.*)

Lenalidomide may also pose a threat similar to that posed by thalidomide. (Compl. ¶ 69.) Celgene developed lenalidomide to treat myelodysplastic syndromes and multiple myeloma, among other disorders, under the brand name Revlimid.

Revlimid, like Thalomid, is distributed pursuant to an FDA-approved REMS system that originally was known as RevAssist®, and is now known as the Revlimid REMS. (*See id.*) Celgene developed several patented methods covering both the Thalomid REMS and Revlimid REMS to ensure that both drugs are delivered safely. (Compl. ¶ 123.)

B. Celgene Obtains a Broad Patent Portfolio on Both Thalomid and Revlimid.

Before selling a new drug in the United States market, brand drug manufacturers like Celgene obtain FDA approval by filing a New Drug Application ("NDA"). (Compl. ¶ 22.) Brand drug manufacturers devote substantial resources to filing an NDA, and before an NDA is approved, the manufacturer must provide the FDA with specific data on safety and effectiveness, including the results of preclinical and clinical testing. (*See id.*) Once the FDA approves an NDA, the manufacturer

must notify the FDA of each patent that "claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug." 21 U.S. C. §§ 355(b)(1). The FDA lists such patents in its publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." There are approximately 30 unexpired patents currently in the Orange Book for Thalomid and Revlimid. *See* Declaration of Gavin J. Rooney (February 3, 2015) ("Rooney Decl."), Exs. 1 & 2.[2]

C. A Generic Manufacturer May File an ANDA, But Remains Subject to the Patent Laws.

Generic pharmaceutical manufacturers can piggyback on brand drug manufacturers' substantial up-front investments by filing an Abbreviated New Drug Application ("ANDA"). (Compl. ¶ 25.) To obtain FDA approval via an ANDA, a generic manufacturer must show, among other things, that its proposed generic drug is "bioequivalent" to the brand name drug. (*Id.*) The ANDA also must show that the

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[2] The documents and facts Celgene cites in the Rooney Decl. are judicially noticeable under Fed. R. Evid. 201(b), because they are "generally known within the trial court's territorial jurisdiction" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." The declaration also attaches certain documents the Court may review because the Complaint relies on them. *See*, *e.g.*, *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1426 (3d Cir. 1997) (on a motion to dismiss, the Court may consider "document[s] *integral to or explicitly relied* upon in the complaint.").

new drug contains the same active ingredients, dosage form, route of administration, strength, and absorption rate as the brand drug. (*Id.*)

Merely filing an ANDA does not provide a generic manufacturer a quick or easy path for bringing generic drug to market. When a generic company files an ANDA, it must submit certifications with respect to each patent listed in the Orange Book for the drug it seeks to mimic. (Compl. ¶¶ 29-30.) The Hatch-Waxman Act specifies four certification alternatives, including a certification that "the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). This is known as a "Paragraph IV Certification."

When an ANDA applicant submits a Paragraph IV Certification, the applicant must provide the patentee with a detailed basis for its belief that the patent is not infringed, is invalid, and/or is unenforceable. 21 U.S.C. § 355(j)(2)(B). If the patentee brings a patent infringement suit against the ANDA applicant within 45 days of receiving notice of a Paragraph IV Certification, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earliest. 21 U.S.C. § 355(j)(5)(B)(iii).

If the patentee does not file suit within 45 days, the FDA may approve the ANDA at any time after completing its review. *Id.* Notably, however, no law (in the Hatch-Waxman Act or otherwise) affects a patentee's right to assert its patents

(whether ever listed in the Orange Book or not) against an ANDA applicant after the 45 days has run. This is true ***regardless*** of whether the brand manufacturer ever filed a patent infringement lawsuit during the first 45 days, and ***regardless*** of whether a 30-month stay ever existed or has expired. Indeed, even when a patentee brings suit against an ANDA applicant during the 45 days, the patentee may continue to assert additional patents against that same applicant at any point during the 30-month stay, or even after the stay has expired.

D. Celgene's Alleged Anticompetitive Acts.

The Complaint includes allegations that are cut and pasted from a number of different complaints that Celgene's competitors filed over the years. In general, these allegations fall into two categories: (1) that Celgene engaged in sham or fraudulent assertion of six specific Distribution Method patents in order to stifle generic competition for Revlimid and Thalomid, and (2) that Celgene prevented its competitors from obtaining samples of Revlimid and Thalomid in order to prevent them from conducting bioequivalence testing, and prevented its competitors from obtaining the active pharmaceutical ingredient for the drugs.

As detailed herein, however, Celgene has a legally protected right to assert nearly three dozen patents, other than the six Distribution Method patents, in its broad patent portfolio covering Revlimid and Thalomid. IUB makes no allegation regarding these nearly three dozen other patents, except that they are generally invalid. (Compl.

¶¶ 225-236, 245.) IUB certainly does not allege that these other patents were fraudulently obtained or asserted in a sham fashion. (*Id.*) In every situation where IUB alleges that Celgene asserted the six supposedly "fraudulent" Distribution Method Patents (Compl. ¶¶ 124-136; 211-238), Celgene also asserted many more patents from within the portfolio. *See Celgene Corporation v. Lannett Holdings, Inc.*, No. 2:15-cv-00697 (SDW)(SCM), Dkt. 1 (D.N.J. Jan. 30, 2015); *Celgene Corporation v. Natco Pharma, Ltd.*, No. 10-5197 (SDW)(MCA), Dkt. 215 (D.N.J. May 6, 2013); *Celgene Corporation v. Barr Laboratories, Inc.*, No. 07-cv-5552 (FLW)(TJB), Dkt. 56 (D.N.J. Dec. 16, 2008).

For ease of reference, the following table lists the majority of Celgene's patents protecting Revlimid and Thalomid:

Patent	Orange Book	Subject Matter	Alleged sham assertion or fraudulently-procured?
5,629,327	Thalomid	Methods of treating unwanted angiogenesis	No
5,635,517	Revlimid	Methods of reducing TNFa; Revlimid Compound	No
6,045,501	Thalomid; Revlimid	Methods of safe distribution and use	Yes
6,255,756	Thalomid	Methods of treating undesired angiogenesis	No
6,281,230	Revlimid	Methods of treating inflammation, autoimmune, oncogenic/cancerous	No
6,315,720	Thalomid; Revlimid	Methods of safe distribution and use	Yes
6,335,554	Revlimid	Revlimid compositions; Methods of reducing TNFa	No
6,561,976	Thalomid; Revlimid	Methods of safe distribution and use	Yes
6,561,977	Thalomid; Revlimid	Methods of safe distribution and use	Yes
6,755,784	Thalomid; Revlimid	Methods of safe distribution and use	Yes
6,767,326	Not Listed	Methods of safe distribution and use	No
6,869,399	Thalomid	Methods of safe distribution and use	No
6,908,432	Thalomid; Revlimid	Methods of safe distribution and use	No
7,119,106	Revlimid	Revlimid pharmaceutical compositions	No
7,141,018	Thalomid	Methods of safe distribution and use	No
7,189,740	Revlimid	Methods of treating MDS	No
7,230,012	Thalomid	Thalomid formulations	No
7,435,745	Thalomid	Methods of treating blood-borne tumors	No
7,465,800	Revlimid	Form B Rev / hemihydrate	No
7,468,363	Revlimid	Methods of treating lymphomas	No
7,709,502	Not Listed	Chirally pure Revlimid	No
7,855,217	Revlimid	Form B Revlimid / hemihydrate (purity)	No
7,874,984	Thalomid	Methods of treating male patients with ENL using REMS	No
7,959,566	Thalomid	Methods of treating male patients with ENL using REMS	No
7,968,569	Revlimid	Methods of treating MM	No
7,977,357	Not Listed	Form A Revlimid & compositions	No
8,858,445	Not Listed	Methods of making hemihydrate/dihydrate Revlimid	No
8,143,283	Thalomid	Methods of treating blood-borne tumors and leukemia	No
8,143,286	Not Listed	Form E / dihydrate Revlimid	No
8,198,219	Not Listed	Compositions containing unsolvated Revlimid	No
8,284,783	Thalomid; Revlimid	REMS (with distribution of Thalomid)	No
8,288,415	Revlimid	Revlimid compound and formulations	No
8,315,886	Thalomid; Revlimid	Methods of safe distribution and use	Yes
8,404,717	Revlimid	Methods of treating anemia due to MDS	No
8,431,598	Not Listed	Form A/unsolvated Revlimid (purity) & compositions	No
8,530,498	Revlimid	Methods of treating MM	No
8,589,188	Thalomid; Revlimid	Methods of safe distribution and use	No
8,626,531	Thalomid; Revlimid	Methods of safe distribution and use	No
8,648,095	Revlimid	Methods of treating MM	No
8,741,929	Revlimid	Methods of treating MCL	No

Rooney Decl., Exs. 3-42.

Celgene listed 33 of these patents covering Revlimid and Thalomid in the Orange Book. (*Id.*) Only six of those 33 are the Distribution Method Patents addressed in the Complaint (*i.e.*, the highlighted entries in the above chart).

ARGUMENT

For an antitrust claim to proceed to discovery, the plaintiff must plead a

plausible theory of liability supported by non-conclusory allegations. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). The plausibility standard is necessary "lest a plaintiff with a largely groundless claim be allowed to take up [discovery]…, with the right to do so representing an *in terrorem* increment of the settlement value." *Twombly*, 550 U.S. at 557-58 (citations and internal quotation marks omitted). The high cost of antitrust cases requires that the "basic deficiency [of a complaint] should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id.* at 558.

A claim is only plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "[A] complaint must allege, in more than legal boilerplate, those facts about the defendants' conduct giving rise to the cause of action." *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *13 (D.N.J. Sept. 15, 2013) (citing *Twombly*, 550 U.S. at 555). "Mere 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Havens v. Mobex Network Servs., LLC*, 2011 WL 6826104, at *3 (D.N.J. Dec. 22, 2011) (citing *Iqbal*, 556 U.S. at 662). Moreover, a court need not accept as true any conclusory statements or "legal conclusions masquerading as facts" in the complaint. *U.S. Claims, Inc. v. Flomenhaft & Cannata, LLC*, 519 F. Supp. 2d 515, 520 (E.D. Pa. 2006) (citing *Morse v. Lower*

Merion School Dist., 132 F.3d 902, 906 (3d Cir. 1997)). Nor need a court accept "conclusory allegations contradicted by documents underlying the complaint." *Flomenhaft*, 591 F. Supp. 2d at 520.

Dismissal with prejudice, and without leave to amend, is warranted where, as here, the defects in the complaint cannot be cured by revised pleading. *Phillips v. Cty. Of Allegheny*, 515 F.3d 224, 236 (3d Cir. 2008) (leave to amend is appropriate following dismissal of complaint, except where "an amendment would be inequitable or futile"); *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002) (same).

I. IUB CANNOT ESTABLISH CAUSATION

Because Celgene has multiple patents that it is legally entitled to assert (and has asserted), IUB simply cannot establish that any of the conduct alleged in the Complaint precluded generic competition for Revlimid and Thalomid. IUB therefore lacks the necessary element of ***causation*** for each of its claims. This threshold deficiency means that IUB cannot state a claim for liability under federal or state law.

And this deficiency affects every alleged theory of liability asserted in the Complaint – all of which are premised on the assumption that there was a generic manufacturer that, but for the alleged misconduct, could have brought generic versions of Revlimid and Thalomid to market. Under the *Noerr-Pennington* doctrine, Celgene has been and remains entitled to assert multiple patents in its portfolio, meaning that no manufacturer could have brought generic versions of Revlimid and

Thalomid to market in any event. *See*, *e.g.*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2007) ("a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing ***and able*** to supply it but for the incumbent firm's exclusionary conduct") (emphasis added) (citing *Atl. Richfield Co. v. USA Petroleum Co.,* 495 U.S. 328, 334 (1990)).

A. IUB Cannot Plead Causation or Injury, Given That Celgene's Patent Portfolio Provides An Independent Bar to Market Entry for Generic Versions of Revlimid and Thalomid.

Under the Supreme Court's *Noerr-Pennington* doctrine, a patentee may assert its patents without fear of liability under the antitrust laws. *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.,* 508 U.S. 49, 55 (1993) ("*PRE*"); *Davric Maine Corp. v. Rancourt,* 216 F.3d 143, 147 (1st Cir. 2000) (the *Noerr-Pennington* doctrine, "which derives from the First Amendment's guarantee of 'the right ... to petition the government for redress of grievances,' U.S. Const. amend. I, shields from antitrust liability entities who join together to influence government action—even if they seek to restrain competition or to damage competitors."); *A.D. Bedell*, 263 F.3d at 250-54; *In re Lipitor*, 2013 WL 4780496, at *21 (citations omitted).

This rule has only two narrowly-defined exceptions. The first is if the patentee "knowingly and willfully misrepresent[ed] facts to the Patent Office," and then later

asserted the fraudulently-procured patent in an infringement suit in an attempt to reduce competition. *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177 (1965). This is known as *Walker Process* fraud and is "sufficient to strip [the patentee] of its exemption from the antitrust laws." *Id.* The second exception is where the patentee objectively knows that the patents are either unenforceable or not infringed, and then asserts the patents anyway (a "sham" assertion) with the subjective intent of reducing competition. *See PRE,* 508 U.S. at 60-61. This is known as the "sham" exception to the *Noerr-Pennington* doctrine. *Id.*

If a plaintiff does not allege that a patent assertion falls within either of the two narrow exceptions to the *Noerr-Pennington* doctrine, then no antitrust liability can attach to that patent's assertion. *See A.D. Bedell*, 263 F.3d at 250-54 (affirming dismissal of antitrust complaint where defendants' complained-of activities were immune from antitrust liability under the *Noerr-Pennington* doctrine); *In re Lipitor*, 2013 WL 4780496, at *21 (dismissing claim based on inadequate allegations of sham and fraud, making defendant-patentee's assertions of patents legal and not anticompetitive); *see also In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000) (absent *Walker Process* fraud or sham patent assertion, "the patent holder may enforce the statutory right to exclude others from making,

using, or selling the claimed invention free from liability under the antitrust laws.").[3]

That Celgene has a relevant patent portfolio of more than forty patents covering Thalomid and Revlimid (33 of which it has listed in the Orange Book as applying to these drugs), *see* Rooney Decl. ¶¶ 1-43, Exs. 1-42, is a fact of which this Court can and should take judicial notice. *See Morris v. Wyeth, Inc.*, 2012 WL 601455, at *5 n.4 (W.D. Lou. Feb. 23, 2012) (taking judicial notice of Orange Book listings).[4]

Of these more than forty patents, however, IUB alleges that just *six* – the Distribution Method Patents – were obtained by fraud or the subject of a sham assertion. (Compl. ¶¶ 123-238.) That leaves almost three dozen other patents that Celgene indisputably may assert to protect its presumptively valid intellectual property, and the expiration dates for those patents range from 2018 through 2028. Rooney Decl., Exs. 3-42. While the Complaint alleges that these patents are "invalid," (*see* Compl. ¶¶ 212, 236, 245), such an allegation is not within any existing exception to the *Noerr-Pennington* doctrine and certainly does not create a new

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[3] *In re Indepent Serv. Orgs. Antitrust Litig.* also discussed an illegal "tying" claim not relevant to this litigation.

[4] Fed. R. Evid. 201(b) permits a court to take judicial notice of facts that are "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," Fed. R. Evid. 201(b), and the United States Patent and Trademark Office is such a source.; *cf. Novartis Pharmaceuticals, Corp. v. Wockhardt USA LLC*, 2013 WL 5770539, at *4-5 (D.N.J. Oct. 23, 2013) (taking judicial notice of FDA letter because it is "a matter of public record…and is relevant to the issues raised in the Motions [to Dismiss]").

exception.

Indeed, as a matter of law, IUB cannot establish that Celgene violated any law by using these presumptively valid patents to exclude infringing products from the market. *Philip Morris Inc.*, 263 F.3d at 250-54; *City of Pittsburgh*, 147 F.3d at 268; *Lipitor*, 2013 WL 4780496, at *21. Again, it is the multiple patents in Celgene's portfolio, which are not challenged as fraudulently procured or sham asserted, that Celgene has asserted and can continue to assert, that explain the absence of generic competition for Revlimid and Thalomid. This means none of the conduct alleged by IUB, including purported fraudulent procurement or sham assertion of the six Distribution Method Patents, could plausibly be treated as the cause. *See*, *e.g.*, *In re Wellbutrin XL*, 2012 WL 1657734, at *27-28 (E.D. Pa. May 11, 2012) (dismissing case where "the plaintiffs have not shown any evidence that the unsuccessful and arguably sham requests in the Citizen Petition actually delayed FDA approval of the generic ANDAs any further than the delay caused by the successful requests").

B. Celgene's Patents Also Preclude Standing For IUB's Antitrust Claims.

For a plaintiff to have standing to pursue an antitrust claim, it must plausibly allege "antitrust injury," which is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 233 (3d Cir. 2013) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). A

complaint must therefore plausibly allege both that the alleged anticompetitive conduct ***caused*** an injury, and that the conduct ***illegally harmed competition***. *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990); *Abbott Labs*, 707 F.3d at 232-33.[5]

If a plaintiff fails plausibly to allege injury flowing from the alleged anticompetitive act, then its complaint must be dismissed. *See, e.g., A.D. Bedell Wholesale Co., Inc. v. Philip Morris Inc.*, 263 F.3d 239, 250-54 (3d Cir. 2001) (affirming dismissal of antitrust complaint where defendants' complained-of activities were immune from antitrust liability under the *Noerr-Pennington* doctrine); *City of Pittsburgh v. West Penn Power Comp.*, 147 F.3d 256, 268-69 (3d Cir. 1998) (affirming dismissal of complaint where plaintiff failed to establish causation of antitrust injury, because plaintiff did not show it could have entered the alleged market under an existing statutory scheme); *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *21 (D.N.J. Sep. 5, 2013) (dismissing claim where allegations of fraudulent procurement, and sham assertion of patents were inadequate because they merely asserted that the patentee asserted its presumed-valid patents in infringement litigation

[5] This requirement is derived from the principle that the antitrust laws were enacted for "the protection of competition, not competitors." *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962); *see also ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 344 (3d Cir. 2012) ("The Sherman Act 'directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.'") (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)).

and by listing them in the Orange Book).[6]

It is well settled that antitrust standing is "a threshold, pleading-stage inquiry and when a complaint by its terms fails to establish this requirement [the court] must dismiss it as a matter of law." *Gatt Commc'ns, Inc. v. PMC Assocs. L.L.C.*, 711 F.3d 68, 75 (2d Cir. 2013) (quoting *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 450 (6th Cir. 2007) (en banc)); *City of Pittsburgh*, 147 F.3d 256, 264-65 (3d Cir. 1998) (dismissing complaint for lack of standing and noting that the "threshold" standing inquiry

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[6] Relatedly – and particularly relevant where IUB has alleged that potential producers of Revlimid and Thalomid would have sold generic versions of the drugs, all of which would infringe the almost three-dozen patents in Celgene's portfolio other than the six Distribution Method Patents – "the public [i]s not entitled to profit by competition among [patent] infringers." *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907); *see also Hynix Semiconductor Inc. v. Rambus Inc.*, 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("[A]n infringer" has "no legal right to be competing in the product market."); *Monarch Marking Sys., Inc. v. Duncan Parking Motor Maint. Co.*, 1988 WL 5038, at *5 (N.D. Ill. Jan. 19, 1988) ("Neither [plaintiff'] nor consumers have a right to the sale of labels which infringe Monarch's patents."), *partially vacated on other grounds*, 1988 WL 23830 (N.D. Ill. Mar. 8, 1988); Richard A. Posner, *Economic Analysis of Law* 91 (5th ed. 1998) ("We do not want an efficient market in stolen goods."); *cf. Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co*., 113 F.3d 405, 417-18 (3d Cir. 1997) (dismissing antitrust claims where plaintiff could not actually compete with defendant due to state and federal laws, as well as contractual restrictions); *In re Canadian Import Antitrust Litig.,* 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for precluding illegal importation of drugs); *see also, e.g.*, *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (because plaintiff was legally ineligible to compete, "[a]ny injury suffered by RSA is therefore unrelated to AK's allegedly exclusionary conduct …."); *Access Telecom, Inc. v. MCI Telecomms. Corp.,* 197 F.3d 694, 712-13 (5th Cir. 1999) ("If there is no legal U.S. export market…, then there is no antitrust injury."). .

"take[s] on particular significance in the context of the antitrust laws"). This threshold requirement is not satisfied where, as here, a complaint cannot establish that the defendant's alleged misconduct ***caused*** an antitrust injury.

* * *

Given that Celgene's assertion of the non-Distribution Method Patents acts as a bar against any generic versions of Revlimid or Thalomid, IUB has no injury and thus no valid claim, regardless of the liability theory it alleges. *See In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006); *A.D. Bedell*, 263 F.3d at 250-54; *City of Pittsburgh*, 147 F.3d at 267-68; *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *21.

II. IUB IS BARRED FROM PURSUING ITS STATE LAW DAMAGE CLAIMS.

A. IUB Lacks Standing To Pursue Claims Under The Laws of Any States Except Connecticut, Massachusetts, and Nebraska.

To establish Article III standing, the named plaintiffs in a putative class action "must allege and show that they personally have been injured." *Klein v. Gen. Nutrition Cos.,* 186 F.3d 338, 345 (3d Cir. 1999) (quoting *Lewis v. Casey,* 518 U.S. 343, 357 (1996)); *see also Winer Family Trust v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007) ("The initial inquiry…is whether the lead plaintiff[s] individually ha[ve] standing, not whether or not other class members have standing.")

Indirect purchasers, such as IUB here, "lack standing to assert claims under the

laws of the states *in which they do not reside* or *in which they suffered no injury*." *In re Packaged Ice Antitrust Litig.,* 779 F. Supp. 2d 642, 657 (E.D. Mich. 2011) (emphasis added); *see also In re Magnesium Oxide Antitrust Litig.,* 2011 WL 5008090, at *10 (D.N.J. Oct. 20, 2011) (dismissing all claims from states with no connection to named plaintiffs).

The alleged injury in this case is paying too much for Revlimid and Thalomid (*see* Compl. ¶¶ 264-65). IUB could only have suffered that injury in states where it paid for Revlimid or Thalomid. *See, e.g., In re Flonase Antitrust Litig.,* 692 F. Supp. 2d 524, 533 (E.D. Pa. 2010) ("Plaintiffs [have] suffered injury and have standing in states where they purchased a drug or reimbursed their members for purchases of a drug."); *see also Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC,* 263 F.R.D. 205, 211-13 (E.D. Pa. 2009); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 155-58 (E.D. Pa. 2009); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1107 (N.D. Cal. 2007); *In re Terazosin Hydrochloride Antitrust Litig.,* 160 F. Supp. 2d 1365, 1370-72 (S.D. Fla. 2001).

Here, the Complaint expressly states that IUB's principal place of business is Connecticut, and that IUB "purchased and/or provided reimbursement for some or all of the purchase price for Revlimid and Thalomid, other than for re-sale, for its members in Massachusetts and Nebraska." (Compl. ¶ 12.) Accordingly, at best, IUB could only bring its state law claims here under Connecticut, Massachusetts, and/or

Nebraska law. Thus, as a threshold matter, any claims in IUB's I, II, III and V causes of action alleged under the laws of any other states should be dismissed.

B. Under Governing New Jersey Choice of Law Principles, All of IUB's State Law Claims Should Be Governed by Connecticut Law, Which Preludes Indirect Purchaser Claims.

Under New Jersey choice of law principles, which apply here, any claims related to IUB's purchases or reimbursements are governed by the law of Connecticut – the State identified in the Complaint as IUB's principal place of business. Given that Connecticut does not permit an indirect purchaser such as IUB to pursue antitrust claims, even under the State's consumer protection law, *Vacco v. Microsoft Corp.*, 793 A.2d 1048, 1050, 1063-68 (Conn. 2002), all of IUB's state law competition and consumer protection claims (Compl. ¶¶ 282-299) must be dismissed.

New Jersey choice of law rules apply here because IUB filed this case in the District of New Jersey. *See In re K-Dur Antitrust Litig.*, 2008 WL 2660783, at *3-5 (D.N.J. Mar. 19, 2008) ("*K-Dur 2008*"). As the *K-Dur 2008* Court explained:

> New Jersey applies a governmental interest choice of law analysis. Where a conflict exists between the laws of the interested states, the court must identify the governmental policies underlying the law of each state and how these policies are affected by each state's contacts to the litigation and the parties. The court must apply the law of the state with the greatest interest in governing the particular issue.

Id. at *4 (internal citations and quotations omitted).

Under these principles, Connecticut has the greatest interest in application of its law here, and any argument by IUB that Massachusetts or Nebraska law applies

instead should be rejected. The Complaint here focuses solely on the alleged overcharges ***IUB*** and other similarly situated ***end-***payors incurred. (Compl. ¶¶ 6, 252.) IUB's alleged injury – *i.e.*, ***its own*** alleged over-payment for its member's purchases – thus occurred in Connecticut, where it drew down from its corporate treasury. *See, e.g., K-Dur 2008*, 2008 WL 2660783, at *3-5 (under New Jersey choice of law principles, applied law of plaintiff funds' home state, because funds' alleged injury was the amount they overpaid when reimbursing their members for drug prices). Other courts applying a governmental interest analysis (albeit under the choice of law principles of states other than New Jersey) have reached the same conclusion. *See, e.g., In re Rezulin Prods. Liability Litig.*, 392 F. Supp. 2d 597, 611 & n.85 (S.D.N.Y. 2005) ("The only injury asserted here – the loss ES allegedly suffered when it overpaid for diabetes drugs – occurred in New York," where ES was located); *Am. Rockwool, Inc. v. Owens-Corning Fiberglass Corp.*, 640 F. Supp. 1411, 1429 n.8 (E.D.N.C. 1986) ("multistate tortious conduct injures a plaintiff at its principal place of business where it loses profits."); *see generally* Restatement (Second) of Conflict of Laws §145, cmt. e (when the plaintiff's "interest is a business or financial one, *such as in the case of unfair competition*, … the place of business is the more important contact.") (emphasis added); *Sergeants Benev. Ass'n Health & Welf. Fund v. Sanofi-Aventis U.S. LLP*, 2012 WL 4336218, at *5 (E.D.N.Y. Sept. 17, 2012); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. at 1107; *In re Lorazepam & Clorazepate Antitrust*

Litig., 295 F. Supp. 2d 30, 50 (D.D.C. 2003).

For these reasons, Connecticut law clearly applies and precludes any state law claim here.[7]

C. Massachusetts Law Also Precludes IUB's Indirect Purchaser Claims.

While New Jersey choice of law rules compel application of Connecticut law, as discussed above, Massachusetts Law also precludes an indirect purchaser, such as IUB, from pursuing antitrust claims.

Here, IUB alleges a cause of action under Mass. Gen. L. Ch. 93A. Although the Complaint does not specify which section of that statute IUB actually invokes, there are only two that provide civil relief: § 9 and §11. And the statute makes clear that a business such as IUB may only bring claims under § 11. As the Supreme Judicial Court of Massachusetts explained in *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 762 N.E.2d 303 (2001), businesses may not bring claims under § 9. *Id.* at 308; *see*

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[7] While some other Courts have permitted an indirect purchaser to pursue state law claims under the law of both is home state and the state in which it reimbursed the costs of a drug, *see*, *e.g.*, *In re Suboxone Antitrust Litig.*, 2014 WL 6792663, at *23 (E.D. Pa. Dec. 3, 2014) ; *Wellbutrin XL*, 260 F.R.D. at 156-57, Celgene respectfully submits that such cases wrongly decided this issue. In *Suboxone*, for example – which relied upon *Wellbutrin XL* and similarly-decided cases – the Court applied laws of the states where reimbursements were made under the theory that such laws are designed to protect consumers within their borders. *Suboxone*, 2014 WL 6792663, at *23. But the "consumer" in this context is not the fund member that uses the drugs, but the fund itself, which alleges that it overpaid. It follows that the fund's home state law is the only appropriate to apply.

also United Food & Commer. Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc., __ F. Supp. 3d __, 2014 WL 6465235, at *25 (N.D. Cal. Nov. 17, 2014) ("Because the EPPs at issue…were acting in trade or commerce when they indirectly purchased or reimbursed their employee or members, they cannot state a claim under § 9 of the Massachusetts consumer protection statute for antitrust injury.")

Under § 11, however, which applies to a business such as IUB, indirect purchaser claims are forbidden. *See In re Suboxone Antitrust Litig.*, 2014 WL 6792663, at *28 (E.D. Pa. Dec. 3, 2014) ("The state legislature has extended *Illinois Brick*'s prohibition on suits by indirect purchasers to §11 of Massachusetts' consumer protection law.")

D. IUB's State Law Claims Fail for the Additional Reason That IUB's "Sham" and "Inequitable Conduct" Allegations Are Preempted Under State Law.

IUB's state law claims must be dismissed for the additional and independent reason that they are preempted by federal patent law, to the extent they are based on allegations that the six Distribution Method Patents were procured through inequitable conduct or the subject of sham assertions.

"[State law c]laims that are predicated on no more than bad-faith misconduct or fraud before the PTO or that are identical in scope to an inequitable conduct defense are preempted by federal patent law." *In re Netflix Antitrust Litig.*, 506 F. Supp. 2d

308, 319 (N.D. Cal. 2007) (citing *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1382 (Fed. Cir. 2000)). This means that indirect purchaser state law claims, like those here, based on alleged sham litigation and/or Orange Book listings must be dismissed insofar as they rely on such allegations. *See*, *e.g.*, *cf. Daiichi Sankyo, Inc. v. Apotex, Inc.*, 2009 WL 1437815, at *9 (D.N.J. May 19, 2009) (dismissing indirect purchasers' state law claims on preemption grounds, because the defendant's patent infringement litigation and Orange Book listings were only wrongful if patents had been wrongfully obtained); *In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *23-25 (D.N.J. Mar. 1, 2007) ("*K-Dur 2007*") (same); *In re Ciprofloxacin Antitrust Litig.*, 363 F. Supp. 2d 514, 542-547 (E.D.N.Y. 2005) (same).

In *K-Dur 2007*, the Court held that the indirect purchaser plaintiffs' state law *Walker Process* and sham litigation claims were preempted by federal patent law. *K-Dur 2007*, 2007 WL 5297755, at *23-25. The allegations in *K-Dur* "specifically relate[d] to [the defendant's] alleged unlawful conduct in obtaining [the patent at issue] through fraud on the PTO" and therefore required dismissal. *Id.* at *24. This is analogous to the present case, because IUB's "sham" allegations are entirely predicated on challenging the enforceability and validity of Celgene's patents. (Compl. ¶¶ 123-237, e.g. ¶ 134 ("The Distribution Method Patents and the '886 patent were obtained from the USPTO through knowing and willful fraud and are unenforceable.").) Included in these allegations is the claim that Celgene could not

invoke the Distribution Method Patents in Orange Book listings and/or litigation against competitors. (*Id.* at ¶¶ 192-195.) Accordingly, just like in *K-Dur 2007*, IUB's sham and *Walker Process* allegations are entirely preempted.

E. IUB's Claim For Unjust Enrichment Fails

IUB's state law claim for unjust enrichment fails for two equally fundamental reasons: (1) an unjust enrichment claim cannot act as an "end run" around a state's bar against indirect purchaser claims, and (2) such a claim could never be certified under Rule 23(a)(2).

Where, as here, an unjust enrichment claim is premised entirely on allegations that the defendant violated the antitrust laws, a plaintiff cannot bring such a claim under the laws of states that do not permit indirect purchasers to pursue antitrust damages claims. *See K-Dur 2008*, 2008 WL 2660780, at *5-6 (dismissing unjust enrichment claims from states that do not provide for indirect purchaser antitrust claims or do not recognize a private antitrust cause of action, because plaintiff "cannot use its unjust enrichment claim as a means to pursue damages that are not allowable under those states' antitrust laws") (collecting cases); *Aikens v. Microsoft Corp.,* 159 Fed. Appx. 471, 477 (4th Cir.2005) (Because plaintiffs cannot sue under their state antitrust laws, "they cannot employ a subsidiary unjust enrichment claim to circumvent this rule."); *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 211 (D. Me. 2004). For the reasons discussed above, Connecticut

law governs IUB's state law claims here, and Connecticut law does not permit IUB to make an indirect purchaser antitrust claim. Accordingly, IUB cannot proceed with its unjust enrichment claim either.

Second, and in any event, "[u]njust enrichment is an equitable doctrine that…depends upon the analysis of ***each individual situation***." *See Clay v. Am. Tobacco Co.*, 188 F.R.D. 483, 500 (S.D. Ill. 1999) (citing *Hershey Foods Corp. v. Ralph Chapek, Inc.,* 828 F.2d 989, 999 (3d Cir. 1987)) (emphasis added); *see also Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 184-85 (3d Cir. 2014) ("In sum, the District Court properly found that individual inquiries would be required to determine whether an alleged overbilling constituted unjust enrichment for each class member. Such specific evidence is incompatible with representative litigation."); *Vega v. T–Mobile USA, Inc.*, 564 F.3d 1256, 1274 (11th Cir. 2009) (unjust enrichment claims require the reviewing court to "examine the particular circumstances of an individual case and assure itself that, without a remedy, inequity would result or persist," and therefore "courts...have found unjust enrichment claims inappropriate for class action treatment").

In the class context, this means that the individualized, plaintiff-by-plaintiff nature of the unjust enrichment inquiry necessarily predominates over common issues because the Court must assess, on a class member-by-class member basis, whether the alleged injuries were unjust ***to that class member***. *See Grandalski*, 767 F.3d at 184-

85. This highly individualized inquiry normally precludes class certification of unjust enrichment claims, and thus it is appropriate to dismiss such claims at the 12(b)(6) stage when alleged on behalf of a class. *See, e.g., Green v. Green Mountain Coffee Roasters, Inc.*, 279 F.R.D. 275, 285 (D.N.J. 2011) (dismissing class action complaint on motion to dismiss, because unjust enrichment claims "will require this Court to undergo an individualized inquiry into the circumstances of each class member," which means the "claim does not lend itself to class treatment"); *In re Polyurethane Foam Antitrust Litig.*, 799 F. Supp. 2d 777, 786 (N.D. Ohio 2011) (dismissing putative indirect purchaser class's unjust enrichment claim on the same basis).

III. IUB ALSO FAILS ADEQUATELY TO ALLEGE THAT CELGENE'S ASSERTIONS OF THE SIX DISTRIBUTION METHOD PATENTS WERE ILLEGAL.

Because , as discussed above, the claims here can all be dismissed on the dispositive grounds of lack of causation, injury and standing, this Court need not reach the sufficiency of IUB's factual allegations about the six Distribution Method Patents. Notably, however, those allegations also are insufficient to state a claim.

Specifically, the Complaint alleges that Celgene obtained the six Distribution Method Patents by fraud on the PTO (by failing to disclose prior art), and that Celgene's assertions of those patents thereafter were a sham. (Compl. ¶¶ 132-34.) But IUB wholly fails to satisfy the heightened pleading requirements for *Walker Process* fraud and sham assertion claims.

Any claim of fraud on the PTO must satisfy the pleading specificity standards of Fed. R. Civ. P. 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). Among other things, a party claiming such fraud must allege with particularity how and why, but for the allegedly omitted prior art – such as that which IUB claims Celgene withheld from the PTO during the prosecution of the Distribution Method Patents (Compl. ¶¶ 123-210) – the patent examiner would not have issued the patent claim. *See Exergen*, 575 F.3d at 1329-30 (pleading failed to state inequitable conduct defense, because it failed to allege with particularity why alleged prior art was material and not cumulative); *see also Therasense*, 649 F.3d at 1291 ("This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.").

The Complaint here identifies a number of claimed pieces of prior art to the Distribution Method Patents, but it never explains how any of them materially differ from, and/or were not cumulative of, the prior art that Celgene did disclose to the PTO during the prosecution of those patents. (Compl. ¶¶ 123-210.) Nor does the Complaint explain how the claimed pieces of prior art are materially similar to, and/or

anticipatory of, any of the specific claims in the Distribution Method Patents. (*Id.*)[8]

Nevertheless, the Complaint asserts in conclusory paragraphs, without further explanation, that these pieces of prior art would have been but-for material to a patent examiner. (Compl. ¶¶ 136, 183-186, 198-200.) This consistent lack of detail renders the allegations completely inadequate to state a valid fraudulent procurement claim (even to the extent IUB was not preempted from basing its state law claims on such allegations). *See Exergen*, 575 F.3d at 1329 (pleading failed to state an inequitable conduct defense because, among other tings, it "fails to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found" and "states generally that the withheld references are 'material' and 'not cumulative to the information already of record,' but does not identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record") (internal citations omitted).

As to the alleged sham assertions of the patents, the *Noerr–Pennington* doctrine does not apply to actions that are "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor."

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[8] One notable example of IUB's failure to plead inequitable conduct with particularity is in its reference to an "Exhibit A" on invalidity. (Compl. ¶ 199.) Exhibit A does not exist. Celgene's research indicates that this was likely a result of IUB's cutting and pasting the allegations, referring to an Exhibit A, from Natco's complaint in Celgene's infringement lawsuit against that manufacturer.

Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). The Supreme Court has established a two-pronged inquiry for determining whether petitioning activity is "sham": a plaintiff must show that defendant's petitioning activity is, first, "objectively baseless," and second, subjectively a concealed attempt to stifle competition. *PRE,* 508 U.S. at 60-61. In order to attempt to meet the "objective baselessness" prong of this inquiry, IUB effectively alleges that Celgene engaged in inequitable conduct before the PTO with respect to the Distribution Method Patents. "Inequitable conduct" is a judge-made equitable doctrine that renders unenforceable any patent that was procured through equitably wrongful means. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). Most often, this is proven by demonstrating that, during the patent prosecution process, a prospective patentee withheld or misrepresented "prior art" that would render one or more of the patent's claims invalid. *Id.* at 1290-91. Courts have recognized that the misconduct portion of an inequitable conduct claim and the fraud portion of a *Walker Process* fraud/sham assertion claim substantially overlap. *See*, *e.g.*, *TransWeb, LLC v. 3M Innovative Properties Co.*, 16 F. Supp. 3d 385, 407 (D.N.J. April 21, 2014) (factual findings supporting inequitable conduct would permit a reasonable jury to conclude that the defendant engaged in *Walker Process* fraud); *Procter & Gamble Co. v. CAO Group, Inc.*, 2013 WL 6061103, at *2 (S.D. Ohio Nov. 18, 2013) ("there is a considerable overlap between the issues of inequitable conduct

and fraud necessary to establish a *Walker Process* antitrust claim"). The claims are thus often analyzed under the same pleading analysis. *Id.*

Numerous courts have dismissed sham litigation claims based on inadequate allegations of any underlying fraud, such as exist here. *See, e.g.*, *Honeywell Intern. Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 1000-01 (Fed. Cir. 2007) (after affirming the district court's determination that Honeywell did not engage in inequitable conduct, concluding that Universal's allegations of sham litigation on the related patent were without merit); *Lipitor*, 2013 WL 4780496, at *21 ("listing presumptively valid patents in the Orange Book and enforcing them against infringers are not bases for an antitrust claim"); *TRW Financial Systems, Inc. v. Unisys Corp.*, 835 F. Supp. 994, 1014 (E.D. Mich. 1993) (patent litigation was not a sham where, among other things, "the Court has found no fraudulent procurement in this case."). Celgene respectfully submits that dismissal of IUB's claims regarding the six Distribution Method Patents is also warranted here.

IV. IUB CANNOT STATE A CLAIM BASED ON CELGENE'S ALLEGED REFUSAL TO DEAL WITH ITS COMPETITORS.

The Complaint alleges that Celgene violated the antitrust laws by refusing to sell samples of Revlimid and Thalomid to companies seeking to sell generic versions of Celgene's drugs. (Compl. ¶¶ 88-121.) The refusal is unlawful, IUB alleges, because the generics are otherwise unable to enter the market to compete. Even if this were true, IUB's claims based on such a unilateral refusal to deal would fail to state a

claim: "[A] complaint . . . which takes the form 'X is a monopolist [and] X didn't help its competitors enter the market so that they could challenge its monopoly . . .' does not state a claim under Section 2. The reason is because the antitrust laws do not impose that kind of affirmative duty . . . ." *Goldwasser v. Ameritech Corp.,* 222 F.3d 390, 400 (7th Cir. 2000).

The Supreme Court has repeatedly reaffirmed that, "as a general matter, the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaging in an entirely private business, freely to exercise his own independent discretion as to the parties with whom he will deal.'" *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)). In *Trinko*, the Supreme Court held that AT&T could not be liable for refusing to provide rivals access to its DSL framework in the absence of an antitrust "duty to deal." *Id.* at 415-16; *see also Pacific Bell Telephone Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 442-43, 450-51 (2009).

In *Trinko* and *Linkline*, the Court emphasized that *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) – the only instance where the Supreme Court has ever found a unilateral refusal to deal anticompetitive – was "at or near the outer boundary of § 2 liability." *Trinko*, 540 U.S. at 409. In *Aspen*, the alleged monopolist had (1) terminated a long-running, prior course of dealing with its rival, and (2) sacrificed short-run profits by refusing sales without any rational business

justification (other than the harm to its rival). *See id*. (describing *Aspen*); *Linkline*, 555 U.S. at 448. As a result, the holdings from every Circuit Court to address the issue since *Trinko* and *Linkline* confirm that the allegations of this Complaint do not meet the test for an actionable refusal to deal.

First, IUB nowhere alleges that Celgene and any of its potential generic competitors had a prior course of dealing with respect to Revlimid or Thalomid. (Compl. ¶¶ 70-122.) That alone is sufficient for dismissal. *In re Elevator Antitrust Litig.*, 502 F.3d 47, 52 (2d Cir. 2007) ("But because plaintiffs do not allege that defendants terminated any prior course of dealing – the *sole* exception to the broad right of a firm to refuse to deal with its competitors – the allegations are insufficient to state a unilateral-monopolization claim.") (emphasis added).[9]

Second, even if termination of a prior course of dealing were not required to state an actionable refusal to deal claim, IUB's Complaint fails for the independent

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[9] *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1074 (10th Cir. 2013) ("First as in *Aspen*, there must be a preexisting voluntary and presumably profitable course of dealing between the monopolist and rival."); *LiveUniverse, Inc. v. MySpace, Inc.*, 304 F. App'x 554, 556 (9th Cir. 2008) ("LiveUniverse contends a refusal-to-deal claim does not require 'an affirmative decision or agreement to cooperate' between competitors. LiveUniverse is mistaken."); *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 673 (D.C. Cir. 2005) ("An antitrust claim based upon the defendant's refusal to cooperate with its competitor can withstand a motion to dismiss only when it is alleged…that the defendant had previously 'engaged in a course of dealing with its rivals…."); *Covad Commc'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1049 (11th Cir. 2004) ("*Trinko* now effectively makes the unilateral termination of a voluntary course of dealing a requirement for a valid refusal-to-deal claim under *Aspen*.")

reasons that it does not allege that no legitimate business justification exists for Celgene's alleged failure to help its rivals. Indeed, the Court can take judicial notice of the tragic birth defects and injuries caused by thalidomide in the past, leading the FDA to require a "REMS" safety program before approving sales of either thalidomide or lenalidomide.[10] The Court may also take judicial notice that the laws of certain states, such as California, purport to hold branded manufacturers like Celgene liable for the injuries caused by generic copies of their drugs.[11]

IUB does not allege that these objective concerns do not exist. That is, IUB does not allege that thalidomide poses no danger, or that state products liability laws do not expose Celgene to liability for mistakes that its generic rivals may make. Instead, it claims that Celgene was not sincere in raising those otherwise legitimate concerns. But the test of legitimate business justifications is objective, not subjective, and IUB's assertion that Celgene's concerns were "pretextual" is legally irrelevant.[12]

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[10] *See* http://1.usa.gov/RLxxxL; *cf. Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir. 2004) (taking judicial notice of records available on the PTO website).

[11] *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008) (branded manufacturers liable for injuries caused by generics); *see also, e.g.*, *Dolin v. SmithKline Beecham Corp.*, 2014 WL 804458, at *6-7 (N.D. Ill. Feb. 28, 2014); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 702 (D. Vt. 2010).

[12] *E.g.*, Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 Antitrust L.J. 413, 416-17 (2006) ("[W]hat matters are the objective economic considerations for a reasonable person, and not the state of mind of" the defendant.); IIIA Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 773e, at 255 (3d ed. 2005) ("A legitimate purpose renders any

United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001) ("[O]ur focus is upon the effect of that conduct, not upon the intent behind it."). If objective reasons for the refusal do exist, the refusal cannot be economically "irrational," and hence cannot be exclusionary conduct under Sherman Act § 2. *See, e.g.*, *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 523 (5th Cir. 1999); *Oahu Gas Serv., Inc. v. Pac. Res. Inc*., 838 F.2d 360, 368-70 & n.3 (9th Cir. 1988) (reversible error to instruct jury that it should "determine if the challenged conduct is supported by legitimate business reasons *or* whether it was a deliberate effort to injure a smaller rival.").

Thus, all claims based on Celgene's alleged refusal to deal should be dismissed.[13]

CONCLUSION

For all of the foregoing reasons, Celgene respectfully submits that the Complaint should be dismissed, without leave to amend.

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accompanying purpose [to disadvantage rivals] irrelevant; regardless of motive, no firm has a general duty to injure itself in order to benefit a rival.").

[13] Celgene recognizes that Judge Salas of this District held otherwise in *Mylan Pharmaceuticals v. Celgene Corporation*, 14-cv-2094-ES, ECF No. 54 (D.N.J. Dec. 22, 2014). There she declined to dismiss the refusal to deal claim of Mylan, one of Celgene's prospective generic competitors cited by IUB here. But Judge Salas conceded that other courts would disagree, and she has certified her decision for an interlocutory appeal to the Third Circuit. *Id.*, Dkt. 69 (Jan. 30, 2015).

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